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APPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/901,310	07	7/09/2001	Alfred S. Despres III	HAYES-707 CON	8573	
	7590	06/30/2003				
Pandiscio & Pandiscio				EXAMINER		
470 Totten Pond Road Waltham, MA 02154				JACKSON, SUZETTE JAMIE		
				ART UNIT	PAPER NUMBER	
•				3738	10	
				DATE MAILED: 06/30/2003	V •	

Please find below and/or attached an Office communication concerning this application or proceeding.

			Υ.K				
	Application No.	Applicant(s)					
000000000000000000000000000000000000000	09/901,310	DESPRES ET AL.					
Office Action Summary	Examiner	Art Unit					
	Jackson J Suzette	3738					
The MAILING DATE of this communication appeared for Reply	ppears on the cover sheet v	vith the correspondence address					
A SHORTENED STATUTORY PERIOD FOR REPI THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a re  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statu  - Any reply received by the Office later than three months after the maili earned patent term adjustment. See 37 CFR 1.704(b).  Status	.136(a). In no event, however, may a ply within the statutory minimum of th d will apply and will expire SIX (6) MC te, cause the application to become A	reply be timely filed irty (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).					
1) Responsive to communication(s) filed on <u>08</u>	<u> April 2003</u> .						
2a)⊠ This action is <b>FINAL</b> . 2b)□ T	his action is non-final.						
3) Since this application is in condition for allow closed in accordance with the practice unde							
Disposition of Claims		·					
4) Claim(s) <u>1-5,7,9-23,25,27-41,43,45-54 and 1</u>	76-78 is/are pending in the	application.					
4a) Of the above claim(s) is/are withdr	awn from consideration.						
5)⊠ Claim(s) <u>76-78</u> is/are allowed.	Claim(s) <u>76-78</u> is/are allowed.						
6)⊠ Claim(s) <u>1-5, 7, 9-23, 25, 28, 31-41, 43, 46, 4</u>	☑ Claim(s) <u>1-5, 7, 9-23, 25, 28, 31-41, 43, 46, 4954</u> is/are rejected.						
7)⊠ Claim(s) <u>9,11,12,27,30,39,47 and 48</u> is/are o	bjected to.						
8) Claim(s) are subject to restriction and	or election requirement.						
Application Papers							
9) ☐ The specification is objected to by the Examir 10) ☐ The drawing(s) filed on is/are: a) ☐ acc		the Eveniner					
Applicant may not request that any objection to 1							
11) The proposed drawing correction filed on	<del>-</del> , .	<del>-</del>					
If approved, corrected drawings are required in r							
12) The oath or declaration is objected to by the E	• •						
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign	an priority under 35 U.S.C	. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority docume	nts have been received.						
· · · · · · · · · · · · · · · · · · ·							
3. Copies of the certified copies of the pri application from the International E * See the attached detailed Office action for a list	iority documents have bee Bureau (PCT Rule 17.2(a))	n received in this National Stage					
14) Acknowledgment is made of a claim for domes	·						
a)   The translation of the foreign language p	rovisional application has	been received.					
15) Acknowledgment is made of a claim for dome	stic priority under 35 U.S.	C. §§ 120 and/or 121.					
Attachment(s)	<b>∧</b> □						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) Notice	w Summary (PTO-413) Paper No(s) of Informal Patent Application (PTO-152)					

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#### **DETAILED ACTION**

1. Applicant's amendment and response dated 4/8/03 has been received in application serial number 09/901,310. Claims 6, 8, 24, 26, 42, and 44 have been canceled.

## Claim Objections

2. Claim 45 is objected to because of the following informalities: Claim 45 depends from a canceled. Appropriate correction is required. Accordingly, the claim has not been further treated on the merits

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Claim 1 recites the limitation "said biocompatible <u>material</u>" in line 8. There is insufficient antecedent basis for this limitation in the claim.

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### Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- Claims 1-3, 7, 10, 13, 14, 17, 19-21, 25, 28, 31-32, 36-39, 43, 46, 49-50, 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Freeman 4,718,905. Freeman discloses the invention (an implant) as claimed noting figures 4, 6 and 8 comprising: a substrate (haptics 32); a structured surface formed on at least a portion o the substrate (wherein it is inherent that the structured surface are the undercuts 42' on the haptic); and a biocompatible coating (42, col. 9,line 30-33) deposited on at least a fraction of the structured surface (see figures. 3, 5 and 7); wherein the structured surface includes a plurality of undercuts (42' col. 12, lines 22-24), and wherein the biocompatible material coats the undercuts and wherein the coating is formed by a thin film technique (col. 11,lines 31-33) adapted to deposit the coating on line-of-sight (col. 10, lines 43-45) hidden surfaces within the plurality of undercuts of the structured surface, wherein the coating is more biocompatible than the structured surface (col. 6, lines 44-53); wherein the film technique includes chemical vapor deposition (col. 11, lines 4); wherein the coating includes titanium (col. 11, line3 22); and a multiple of layers (col. 10, line 65); and positioning the implant in a vertebrate in need thereof.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 4-5, 16, 18, 22-23, 34-35, 40-41, 52, 54 rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Homsy 5,176,712. Freeman's coating has been disclosed above, however the coating of Freeman is applied to a haptic and Freeman does not disclose a coating that is softer then the structured surfaces or softer than the structured substrate. Homsy teaches an orthopedic endoprosthesis where at least a portion of the proximal surface is biocompatible, porous, deformable and allows for tissue-growth promoting and another portion of the proximal surface is biocompatible, porous non-deformable and tissue in-growth promoting thus making the biocompatible coating more biocompatible than the substrate. (See col. 2, line 8-12 and col. 5, lines 47-51 figures 10c). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating materials utilizing thin film and line-of-sight techniques disclosed by Freeman and/or amounts to supply softer coatings as taught by Homsy to further allow for tissue in-growth and/or on growth to make the prosthesis adhere to the patients remaining tissue.
- 10. Claims 15, 33, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Arpac et al. 6,291,070. Freeman has been disclosed however Freeman does not specify the use of nano layers. Arpac teaches substrate coatings which utilize nano particles

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to for layers (see col. 7, lines 61-67 and col. 12, line 12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the nano layers of Arpac et al. in conjunction with the coating techniques of Freeman in order to provide a material which evenly distributed coating substrate applications.

## Allowable Subject Matter

- 11. Claims 9, 11-12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
- 12. Claims 9, 11-12, 27, 29-30, 47-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 13. Claims 76-78 are allowed.

## Response to Arguments

14. Applicant's arguments with respect to claims 1-10, 12-28, 30-46, and 48-54 have been considered but are moot in view of the new ground(s) of rejection.

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#### Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Roth 6,527,919 and Roth 6,096,175 show closely related material.

- Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- 18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

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- 19. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3580.
- 20. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Suzette J. Jackson

23 June 2003

David H. Willse Primary Examiner